

**REMARKS**

Claims 1, 9-10, 12-13, and 15-25 are pending. Claims 2-8, 11, and 14 are canceled. Applicants reserve the right to pursue the subject matter of any canceled claims in one or more continuing applications.

**Support for Amendments**

The listing of claims appears in this paper for convenience. No amendments to the claims are made in this paper.

The specification is amended to remove the word “New” from the title and to correct obvious typographical errors. Support for the amendments can be found in the specification as filed, for example in the term “perfluoroheptanoic” at page 15; in compound 11 in Table VI at page 53, line 9; and in compound 56 in Table VI at page 55, line 16.

No new matter is entered.

**Restriction and Election of Species Requirement**

In response to the Restriction Requirement of June 2, 2009 requiring restriction between Group I (claims 1, 9-10, 12-13, and 15-23) and Group II (claims 24-25), Applicants elected Group I (claims 1, 9-10, 12-13, and 15-23, drawn to compounds/compositions), with traverse. In response to the Election of Species Requirement, Applicants elected [Nε(Me)<sub>3</sub>-Lys<sup>8</sup>, (4S)-MeHex<sup>14</sup>]-KF, which is compound 93, disclosed in Example 10, with traverse. The Office Action makes the Restriction Requirement final. Applicants respectfully traverse the position of the Office Action with respect to the interpretation of the claim language, as discussed below with regard to the rejection of the claims.

However, having found the elected species allowable, the Office Action extends the search and examination to other species. In the event of the allowance of a generic claim, Applicants respectfully request rejoinder of claims 24-25.

### **Information Disclosure Statement**

An English translation of pages 29-106 of the thesis of Carlos Jimenez Garcia is submitted in a supplemental Information Disclosure Statement for the Examiner's consideration

### **Objections to the Specification**

The Office Action objects to the term "New" in the title. By amendment, the term "New" is removed from the title.

The Office Action objects to the last entries in the Tables on pages 39 and 42 as being cut-off. By amendment, the typographical errors are corrected.

The Office Action objects to the use of commas in various locations on pages 62-80 rather than periods. Applicants respectfully traverse the suggestion of the Office Action to replace the commas with periods. The use of the commas is conventional according to British/European usage. Applicants note the following guidance from the MPEP:

Examiners should not object to the specification and/or claims in patent applications merely because applicants are using British English spellings (e.g., colour) rather than American English spellings. It is not necessary to replace the British English spellings with the equivalent American English spellings in the U.S. patent applications. Note that 37 CFR 1.52(b)(1)(ii) only requires the application to be in the English language. There is no additional requirement that the English must be American English.

(MPEP 608.01). Applicants submit that the objection to the use of commas is not consistent with USPTO policy as set forth in the MPEP.

The Office Action objects to the lack of page numbers in the specification as filed. Applicants respectfully request that the suggestion to add page numbers be withdrawn as being unnecessary since the application has already been reviewed for formalities by OIPE and published as US Published Application 2007/0117743, demonstrating that a substitute specification to include page numbers is not necessary for the Publications branch of the USPTO.

### **Rejection Under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph**

Claim 21 is rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as allegedly being indefinite due to the notation “(4RS)” and the term “Pfh” (see OA, p. 6). Applicants respectfully traverse.

The notation “(4RS)” is an accepted term of art to indicate that the chiral center at position 4 is racemic. See Basic Terminology of Stereochemistry (submitted in the attached supplemental IDS):

#### **Racemate**

An equimolar mixture of a pair of *enantiomers*. It does not exhibit *optical activity*. The chemical name or formula of a racemate is distinguished from those of the enantiomers by the prefix ( $\pm$ )- or *rac-* (or *racem-*) or by the symbols *RS* and *SR*.

(page 2216, emphasis in original).

The term “Pfh-OH” is an abbreviation for “perfluoroheptanoic acid” as indicated on page 15 of the specification. The obvious typographical error on page 15 is corrected in the amendments to the specification above. Moreover, the alternate language presented in the Office Action is not a reasonable interpretation because when amino acids are represented by single letter abbreviations, the convention is to use a capital letter. See “Nomenclature and Symbolism for Amino Acids and Peptides” (submitted in the attached supplemental IDS).

**Rejection Under 35 U.S.C. § 112, 1<sup>st</sup> paragraph**

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as allegedly failing to comply with the written description requirement. The Office Action asserts that the “broadest reasonable interpretation” of the claims includes every conceivable alteration imaginable, including residues, based on the disclosure in the specification on page 19.

Applicants respectfully traverse on the basis that the interpretation adopted by the Office Action is clearly unreasonable, and the impossibly circular nature of such an interpretation is inconsistent with the plain language of the claims. Simply put, the scope of claim 1 does not include compounds that are capable of providing a residue of the compound because claim 1 has been amended to be limited to formula 1, wherein the L-Orn at position 8 is substituted by another natural or non natural amino acid, and/or is masked with one or more substituent organic groups; and wherein the claimed compound may optionally differ from formula 1 by modification of the terminal acyl group; or a pharmaceutically acceptable salt thereof. Applicants respectfully submit that the amendments to claim 1 must be considered, and the scope of claim 1 must be considered accordingly. The terms “derivatives,” “prodrugs,” and “residues” do not appear in the claims, and it is improper for the Office Action to import the terms into the claims. Moreover, the calculation on page 10 of the Office Action relating to the number of compounds generated by replacing 10 of the 14 positions to yield  $20^{10}$  compounds is again clearly improper because it conflicts with the plain language of the claims. The claims require substitution at position 8 and optional substitution at the terminal acyl group, so the discussion in the Office Action of replacing 10 of the 14 positions is not relevant to the claims.

As discussed above, Applicants respectfully traverse the Office Action's position that the language of page 19 of the specification supersedes the clear language of claim 1 introduced by amendment. Accordingly, Applicants respectfully request withdrawal of the rejection.

### **Rejection Under 35 U.S.C. § 101**

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. § 101 as being allegedly directed to non-statutory subject matter. The rejection is based on the Office Action's position that the language of page 19 of the specification supersedes the clear language of claim 1 introduced by amendment. Applicants respectfully traverse for at least the same reasons as discussed above with respect to written description. The Office Action improperly ignores the actual language of the claims, which have been amended to be limited to formula 1, wherein the L-Orn at position 8 is substituted by another natural or non natural amino acid, and/or is masked with one or more substituent organic groups; and wherein the claimed compound may optionally differ from formula 1 by modification of the terminal acyl group; or a pharmaceutically acceptable salt thereof. There is simply no basis for the Examiner's position that such language could possibly include the amino acid Phe by itself. Accordingly, Applicants respectfully request withdrawal of the rejection.

### **Rejection Under 35 U.S.C. § 102(b)**

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Albericio et al (WO 2001/58934). The rejection is based on the Office Action's position that the language of page 19 of the specification supersedes the clear language of claim 1 introduced by amendment. Applicants respectfully traverse for at least the same reasons as

discussed above with respect to written description and non-statutory subject matter. The Office Action improperly ignores the actual language of the claims, which have been amended to be limited to formula 1, wherein the L-Orn at position 8 is substituted by another natural or non natural amino acid, and/or is masked with one or more substituent organic groups; and wherein the claimed compound may optionally differ from formula 1 by modification of the terminal acyl group; or a pharmaceutically acceptable salt thereof. There is simply no basis for the Examiner's position that such language could possibly include the amino acid Phe by itself (see Office Action, page 14, last line). With respect to the compound named at page 14, lines 19-21, Applicants note that the Thr(tBu) at position 12 precludes the compound from meeting the limitations of claim 1, which require an unsubstituted Thr at position 12. As a further example, claim 15 lists 11 species of claimed compounds, none of which are even remotely related to the amino acid Phe by itself. Applicants respectfully submit that the Office Action has failed to provide any reasoning as to how the 11 species of claimed compounds in claim 15 are anticipated by the amino acid Phe. Accordingly, Applicants respectfully request withdrawal of the rejection.

**Rejection Under 35 U.S.C. § 102(b)**

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Angel Lopez Macia PhD thesis (cited in the IDS dated March 11, 2009). The rejection is based on the Office Action's position that the language of page 19 of the specification supersedes the clear language of claim 1 introduced by amendment. Applicants respectfully traverse for at least the same reasons as discussed above with respect to written description and non-statutory subject matter. The Office Action improperly ignores the actual

language of the claims, which have been amended to be limited to formula 1, wherein the L-Orn at position 8 is substituted by another natural or non natural amino acid, and/or is masked with one or more substituent organic groups; and wherein the claimed compound may optionally differ from formula 1 by modification of the terminal acyl group; or a pharmaceutically acceptable salt thereof. There is simply no basis for the Examiner's position that such language includes the Thr(tBu) at position 12 as cited in the Office Action at page 15, lines 12-13. The compound cited in the Office Action cannot meet the limitations of claim 1, which require an unsubstituted Thr at position 12. As a further example, claim 15 lists 11 species of claimed compounds, none of which are described in the Lopez-Macia thesis. Accordingly, Applicants respectfully request withdrawal of the rejection.

### **Nonstatutory Obviousness Type Double Patenting**

Claims 1, 9-10, 12-13, and 15-23 are rejected based on the judicially created doctrine of nonstatutory obviousness type double patenting over claims 1-49 of U.S. Patent 7,482,429. Applicants respectfully traverse on the basis that the Office Action misinterprets the pending claims. The compound cited on page 17, lines 3-4, of the Office Action is specifically excluded from the pending claims as the cited compound lacks substitution of L-Orn at position 8, which feature is specifically recited in claim 1, and is improperly ignored by the Office Action. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 1, 9-10, 12-13, and 15-23 are rejected based on the judicially created doctrine of nonstatutory obviousness type double patenting over claims 1-13 of copending application 11/587,177. Applicants respectfully traverse on the basis that the Office Action misinterprets the

pending claims. Specifically, the Office Action relies on canceled claim 3 as evidence that the instant claims are not patentably distinct from the claims of the '177 application. Applicants note that claim 3 has been canceled, and the scope of claim 1 has been amended. As such, it is improper for the Office Action to rely on an outdated and canceled claim to determine the scope of the pending claims while ignoring the actual language of the pending claims. Moreover, as the '177 application is still pending and the claims are subject to amendment, Applicants respectfully request that the rejection be held in abeyance pending determination of patentable subject matter.

### AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required for consideration of this paper to Deposit Account No. **50-3732**, Order No. 13566.105010. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 13566.105010.

Respectfully submitted,  
KING & SPALDING, L.L.P.

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